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REMARKS

Reconsideration of this application is respectfully requested in view of the foregoing amendments and the following discussion.

The "interview" granted to applicants' attorney by Examiners Allen and Mahatan is acknowledged with appreciation. Applicants' attorney has not received a copy of the Interview Summary but at least Examiner Allen seemed to question the novelty of remote serological crossmatching as described and claimed. The claims have been amended to further clarify the steps involved in remote serological crossmatching so that the crossmatching can be done by a skilled technician at a single processing laboratory while the actual blood product is placed or resides at the remote patient facility at which the patient is located. This is not even remotely suggested by Cox et al and applicants are not aware of any system that employs remote serological crossmatching as defined. Furthermore, it is simply beyond the comprehension of Cox et al to utilize remote serological crossmatching or of comparing all of the blood attributes, for example, as positively recited in claim 1. It is not a mere matter of choice whether one selects electronic crossmatching or remote serological crossmatching: Not all patients qualify for electronic crossmatching because they only have one blood type or they have antibodies thereby making it necessary to perform serological crossmatching; and by utilizing applicants'

remote serological crossmatching method and system the testing can be performed at the central facility while the blood component is located at the remote facility so as to eliminate the need for transportation after testing has been completed. Other features of determining all blood attributes, managing and tracking are hereinafter discussed in specific relation to the claims but it is believed that the foregoing should be reviewed in light of the Examiner's comments throughout the interview.

Enclosed is a revised set of drawings in response to the Notice of Draftsperson's Patent Drawing Review and which are believed to overcome the objections to the drawings.

Claims 1 to 30 under 35 U.S.C. §112, first and second paragraphs were rejected as containing subject matter not described in the specification so as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention. Secondly, specific reference is made to claims 1, 10 and 12 and their dependent claims for lack of clarity in failing to recite a final process step which agrees back with the preamble. In response, claims 1 and 10 have been amended to delete reference to "programmable" and to recite the step of managing said blood products by preparing a patient identification database of the blood products and patient specimens and storing information which correlates each of the blood products and patient specimens, and further recite the step of tracking the location and movement of each of the blood products and patient specimens between the patient facilities and central blood testing facility by

displaying the information stored in the database relating to their location and movement. Similarly, claim 20 has been amended to identify the managing means and the tracking means. Also, claim 29 has been amended to delete "programmable" and to identify the managing means insofar as it pertains to remote serological crossmatching of each segment and patient specimen.

Claims 1 to 30 also stand rejected under 35 U.S.C. §102(b) as being clearly anticipated by Cox et al. Claim 1 has been amended to recite the steps of remote serological crossmatching each patient specimen and blood product. For example as described at some length in the specification, pages 11 to 14, and shown in Figures 2, 3, 18 and 19, remote serological crossmatching is carried out by providing a patient specimen as well as an inventory of blood products at the central blood testing facility, selecting one of the blood products which has an available segment, detaching the segment from the blood product, transferring the blood product and from the central blood testing facility to one of the remote patient facilities at which the patent is located. In this way, the blood product is available at the remote patient facility and the segment remains with the patient specimen at the central facility for crossmatching. When an order is received for a blood product for a particular patient, serological crossmatching of the patient specimen and assigned segment of the blood product is carried out at the central facility to determine their compatibility with one another. No such capability for remote serological crossmatching exists in Cox et al and particularly the ability to perform a remote serological

crossmatch at a central facility using a segment detached from a blood product which has been transferred to the remote patient facility. Accordingly, crossmatching can be performed at the central facility, referred to as the "central processing laboratory" in Figures 2 and 3 and which has the unique capability of serological crossmatching between a segment of the blood product and patient specimen.

Claim 1 further recites determining all of the blood attributes of each of the blood products and patient specimens as well as determining their compatibility by comparing all of their blood attributes, reference being made to pages 7-8, 14-17 of the specification as well as Figures 4 to 6. To the contrary, Cox et al as well as other blood bank systems only compare ABO/Rh compatibility and check for the presence of other antibodies; however, Cox et al does not actually perform a physical compatibility test in a test tube between the blood product and patient specimen for other blood attributes which is extremely important in a determination of compatibility and a safe blood product for the patient. In Cox et al, there are several references to indicate that they are only electronically comparing the ABO Attributes. According to FDA regulations and the AABB (American Association of Blood Banks) Standards, that is all that is required of an electronic crossmatch -- a comparison of ABO records to insure that they are ABO compatible. Cox et al states "It has been suggested that a computer crossmatch would be a safer system of providing a check of ABO compatibility without the disadvantage of the IS crossmatch." (Page 1360, Column 2, line 9.)

The EBRS system assures only that two blood types have been performed on a patient and that the antibody screen is negative. The antibody screen MUST be negative in order for their system to release a unit through the EBRS. The antibody screen is a test to detect unexpected antibodies. There are over 300 such antibodies identified. If the test must be negative and therefore there are no antibodies present, Cox et al cannot possibly be comparing all of the attributes as performed in applicants' method and system as claimed. Cox et al, page 961, Column 1, lines 17-22 refers to validation of the patient's blood type and negative antibody screen and states further: "validation of the EBRS for determination of the ABO compatibility of the recipient and the donor unit". Clearly there is lacking any suggestion of a way of checking all of the blood attributes.

Claim 1 has been amended also to clarify the step of managing each of the blood products segments and specimens as recited as well as tracking the location and movement of the blood products, segments and specimens between the remote patient facilities and central facility by displaying the information stored in the database; see pages 24-25 and Figures 20 to 22. Cox et al are not confronted with the problem of tracking the location and movement of blood products, segments and patient specimens, since it is not even capable of performing remote serological crossmatching. Furthermore, as the term EBRS suggests, Cox et al are concerned only with releasing the blood product once the electronic crossmatch has been performed for immediate use by the patient. Moreover, applicants' system is capable of recording

information about each and every c ossmatch performed, whether compatible or incompatible, as we l as comparing all blood attributes and of tracking and manac ng same and which steps are clearly lacking in Cox et al for the reasons discussed. In this connection, applicants are not aware of any method or system which has been devised for creating and detaching a segment at one facility for the purpose of remote se ological crossmatching while the blood product resides at the pati ent facility and is available for immediate use.

Claims 2 to 9 are dependen from claim 1 or intervening claims and recite other features of applicants' method which are clearly and patentably distinguish ble over Cox et al. For example, claims 2 and 7 recite othe features of the management process and specifically the step of toring information pertaining to patient needs and history; claim emphasizes further steps of assigning the blood products and pa ient specimens to a location and tracking their movement to othe locations. Claims 4 and 5 emphasize additional features of dis laying the information; claim 6 further details the crossmatchin of segments of each blood product and specimen, assigning to a location and recording the location in the database. Claim 8 em hasizes the step of producing a product identification tag and a taching to each said blood component; and claim 9 emphasize other characteristics of comparing all blood attributes of t e blood products and patient specimens.

Claim 10 has been amended n a manner similar to claim 1

to clarify the managing and tracking steps but also specifies in more detail the steps of assigning a segment of a blood component for crossmatching and remote serological crossmatching each segment and patient specimen at the blood testing facility. As previously discussed, Cox et al is concerned solely with electronic crossmatching so that, as implied by the term Electronic Blood Release System, once the electronic crossmatching is completed, it can be released to the patient. In any event, Cox et al is incapable of remote serological crossmatching of a segment of a blood component and a patient specimen; nor would it have been obvious to one of ordinary skill in the art to substitute remote serological crossmatching for electronic crossmatching which involves a completely different set of problems to overcome in managing and tracking each segment, blood component and patient specimen.

Claims 11 to 20 emphasize other steps of applicants' method and particularly relating to determining the attributes prior to crossmatching, testing their compatibility prior to crossmatching, periodically updating the attributes in claims 11 to 13 and 15. Claims 14 and 16 to 19 are concerned more with tracking and recording information related to each blood product or segment thereof and patient specimen.

Claim 20 has been amended to clarify the means for managing blood product information and for tracking the location and movement of blood products and patient specimens between the patient facilities and blood testing facility. Again, there is

completely lacking in Cox et al any suggestion of managing blood products by entering both blood type information as recited and remote serological crossmatching information; nor is there any suggestion of tracking the location of the blood products and patient specimens as recited

Claims 21 to 26 and 28 recite other features of the managing means primarily directed to recording information relating to the history of each patient, expiration date of patient specimens, comparing blood attributes of each patient specimen and blood product in claim 26, and recording components of blood products and indicating the presence of reserved components in inventory in claim 28.

Claim 29 is directed to a blood management system as recited in combination with means for recording information identifying each patient, obtaining a blood specimen from each patient, assigning a segment of a blood product for crossmatching, serologically crossmatching each segment and patient specimen to determine compatibility, identifying each segment and patient specimen crossmatched, and assigning the segment and specimen to a location in one of the blood test facility and remote patient facilities. As previously discussed in relation to claims 1 and 10, Cox et al is lacking in any suggestion of serological crossmatching or of entering such information and assigning to a location as recited.

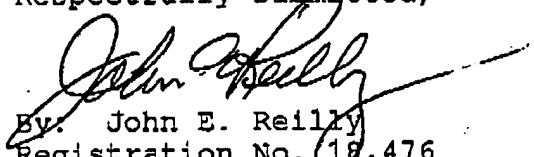
Claims 30 and 31 recite other features of the management

system of claim 29 which are lacking in Cox et al.

The Commissioner of Patents and Trademarks is hereby authorized to charge any additional claim fee which may be due to Deposit Account No. 18-0875.

It is therefore urged that the claims as now presented for consideration are in allowable condition and action to that end is courteously solicited. If any issues remain to be resolved, it is requested that the Examiner contact attorney for applicant at the telephone number listed below.

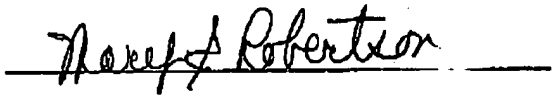
Respectfully submitted,



By: John E. Reilly
Registration No. 18,476
Attorney for Applicants
1554 Emerson Street
Denver, Colorado 8018
Area Code 303 839-8700

CERTIFICATE UNDER 37 C.F.R. 1.8

I hereby certify that the foregoing Amendment is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231, this 28th day of July, 2003.



MARKED UP VERSION OF PARAGRAPHS OF SPECIFICATION:

Page 1, lines 1 (insert as separate paragraph):

Cross Reference to Related Application

This application claims the benefit of Provisional Serial No. 60/193,819 filed 31 March, 2000 for METHOD AND SYSTEM FOR MANAGING BLOOD PRODUCTS, by Miklos Csore et al and owned by the assignee of the present application.

Page 3, lines 17-24:

"Blood Type Definitions": A blood type is a way to classify blood into various groups. A blood type is determined by the presence or absence of antigens on the red blood cells, and the presence or absence of antibodies in the serum. A blood type definition in the computer database is the combination of antibodies and antigens for each blood group (ABO/Rh).

Page 9, lines 11 & 12, and lines 17-19:

Figures 4A and 4B [is] are a flow chart illustrating the logic used in standard compatibility test;

Figures 7A and 7B [is] are a flow chart illustrating the logic used in an emergency patient product compatibility test;

Page 12, lines 27-28 through Page 13, line 11:

Completing the remote crossmatch is the process wherein

a lab technician at the central laboratory L assigns a blood component identified by a segment to a patient specimen. Once the assignment is made, the lab technician proceeds to test the segment with the patient specimen to determine compatibility. Upon completing the crossmatch test, the lab technician enters the results into the computer program database. Once the results are saved, the product ID tag will be printed at the location L of the blood component [L] and the blood component will be ready to issue to the patient [if the patient and product are compatible].

Page 18, lines 2-4:

Button captions of the patient bar P are driven by the current state of patient information which is drawn from the database

MARKED UP VERSION OF CLAIMS:

1. A [programmable] method of managing and tracking blood products between a plurality of remote patient facilities and a central blood testing facility wherein a blood specimen is obtained from each patient who requires a blood reserve for possible transfusion and said specimen is transferred to said central blood testing facility comprising the steps of:

[obtaining a blood specimen from each patient who requires a blood reserve;] providing an inventory of blood products at said central blood testing facility;

selecting [a] one of said blood [product for crossmatching with each said patient specimen] products which has an available segment at said central blood testing facility;

detaching said segment from said blood product at said central blood testing facility;

transferring one of said blood products from said central blood testing facility to one of said remote patient facilities at which said patient is located;

assigning said segment to said patient specimen for crossmatching at said central blood testing facility;

remote serological crossmatching each said patient specimen and said segment of said blood product at said central blood testing facility to determine their compatibility with one another; [and]

determining all of the blood attributes of said one of said blood products and said patient specimen;

determining the compatibility of said one of said

blood products and patient specimen selected by comparing all of said blood attributes thereof;

managing said blood products by preparing a patient identification database of each of said blood products, segments and patient specimens [determined to be compatible] and storing information in said database at each of said central blood testing and remote patient facilities [correlating] which correlates each of said blood products, segments and patient specimens, their location and movement; and

tracking the location and movement of each of said blood products, segments and patient specimens in said database between said remote patient facilities and said central blood testing facility by displaying the information stored in said database relating to their location and movement.

3. The method according to claim 1 including the step of assigning said blood products and said patient specimens to a location within each of said remote patient facilities and said central blood testing facility and tracking any movement of said blood products and said patient specimens to other locations.

4. The method according to claim 1 including the step of [determining types of blood attributes of each of said blood products and said patient specimens] displaying said patient identification information on a computer at each of said remote patient facilities and central blood testing facility.

5. The method according to claim [1] 4 including the

tep of [determining compatibility of s id blood product and said atient specimen by comparing the t es of blood attributes hereof] displaying said information on patient bar on each said omputer which is accessible to all ers regardless of their ocation at each of said facilities.

6. The method according to claim 1 further haracterized by crossmatching a segment of each said blood product d each said patient specimen at sa central blood testing acility, assigning each said segmen and each said patient pecimen to a location in said central blood testing and remote atient facility, and recording said lo ation in said database.

7. The method according to laim [1] 2 including the tep of selectively displaying the absen e or presence of each item f information stored including specia needs, patient comments, rior transfusion reaction history, aut ogous blood availability, irected blood components, blood type , presence of unexpected ntibodies, [and] patient specimen exp ration date and reserved lood components.

8. The method according to laim 1 wherein the step of ross-matching includes the step f producing a product dentification tag and attaching to ach said blood component found to be compatible].

9. The method according t claim [9] 1 [including] wherein the step of determining all the blood attributes is

characterized by comparing the an gens and antibodies in each of said blood products and said patie specimens to determine whether each is present in each segment f said blood product and said patient specimen tested and st ing said information in said database.

10. [In a programmable l ood management system] A method for managing and tracking blood p oducts , patient specimens and segments betwee a plurality of ospitals and a central blood [test] testing facility wherein a mputer database is provided for recording information and a screer is provided for displaying said information, the method comprisin the steps of:

obtaining a bloc specimen from each patient requiring a blood [reserve] prod t to be reserved for possible transfusion;

assigning a segm nt of a blood product for crossmatching;

remote serological crossmatching each said segment and said patient specimen at sa d facility to determine their compatibility with one another;

managing each said egment and said patient specimen crossmatched by identifying each aid segment, said component and said patient specimen [determine to be compatible] with patient identification information a recording said patient identification information on sai database; and

[recording said pa ent identification information on said database]

tracking the locat on and movement of each of said

segments, said products and said patient specimens between said hospitals and said facility.

11. [In a system] A method according to claim 10 further characterized by determining [blood type] all attributes of each of said blood products and said patient specimens prior to said crossmatching.

12. [In a system] A method according to claim 10 including the step of testing the compatibility of said [blood type] attributes prior to said crossmatching.

13. [In a system] A method according to claim 12 characterized by periodically updating said [blood type] attributes and recording said information in said database.

14. [In a system] A method according to claim 10 including the step of tracking the location of each said segment and said patient specimen by recording [its] their movement between said test facility and patient location.

15. [In a system] A method according to claim 10 including the step of recording blood attributes of each said patient specimen in said database.

16. [In a system] A method according to claim 10 including the step of recording prior transfusion reaction history of each said patient in said database.

17. [In a system] A method according to claim 10 including the step of recording autologous blood availability in said database.

18. [In a system] A method according to claim 10 including the step of recording blood type of each said blood product and said patient specimen.

19. [In a system] A method according to claim 10 including the step of recording the specimen expiration date of each said segment and said patient specimen.

20. A system for managing blood products and tracking their movement between a central blood test facility and a plurality of hospitals wherein a computer is provided for processing data including a screen for displaying information, said system comprising:

managing means having first means including a database for entering information pertaining to each patient requiring a blood reserve [;] , second means for entering blood type information for a blood specimen from each said patient [;] , third means for recording a blood type for a blood product assigned to each said patient , fourth means for recording on said database results of comparing blood attributes of each said patient specimen and said blood product ; [and]

[fourth] fifth means for recording on said database results of serological crossmatching of each said patient specimen and said blood product; and

tracking mean for tracking the location and movement of each of said b od products and patient specimens between said blood test faci ty and said hospitals by displaying on said screen the informatio stored in said database relating to their location and movement.

29. [A] In a [prog mmable] blood management system for managing [and tracking] inform tion relating to blood products [for use] between a central blood st facility and one or more remote patient facilities wherein a omputer is provided for processing data, a database is provided or recording said information and a screen is provided for displ ing said information recorded, the improvement comprising:

managing mea including means for recording information identifying each atient requiring a blood reserve on said database [;] , means r obtaining and recording a blood specimen from each said patie [;] , means for assigning a segment of a blood product for cr smatching [;] , means for remote serological crossmatching e h said segment and said patient specimen at said blood t st facility to determine their compatibility with one anoth r [;] , means for identifying each said segment and said pa ent specimen [determined to be compatible;] , and means for ssigning said segment , said blood product and said patient sp imen to a location in one of said blood test facility and said emote patient facilities.